



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-0600]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 28, 2018 to obtain comments from the public and affected agencies. CDC received one non-substantive anonymous comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

CDC Model Performance Evaluation Program (MPEP) for Mycobacterium tuberculosis Drug Susceptibility Testing (OMB Control No.0920-0600, Expires 3/31/2019) - Revision - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Centers for Disease Control and Prevention (CDC).

Background and Brief Description

As part of the continuing effort to support domestic public health objectives for treatment of tuberculosis (TB), prevention of multi- drug resistance, and surveillance programs, CDC is requesting approval from the Office of Management and Budget to continue information collection from participants in the Model Performance Evaluation Program for Mycobacterium tuberculosis Susceptibility Testing. This revision request includes

(a) modification of the Participant Biosafety Compliance Letter of Agreement to contain language to ensure that participants understand and comply with biosafety guidelines using quality management system practices; (b) modification of Instructions to Participants Letter to include detailed instructions for online data entry of DST results; (c) modification of MPEP Mycobacterium tuberculosis Results Worksheet to include fields for entering methods used for conventional and molecular DST; (d) addition of a MPEP Mycobacterium tuberculosis Minimum Inhibitory Concentration

(MIC) Results form for laboratories performing this procedure to enter results manually and submit by email to TBMPEP@cdc.gov; and (e) reduction in request for burden hours from 156 hours to 129 hours due to fewer laboratories participating in the program compared to the previous submission request.

While the overall number of cases of TB in the U.S. has decreased, rates still remain high among foreign-born persons, prisoners, homeless populations, and individuals infected with HIV in major metropolitan areas. To reach the goal of eliminating TB, the Model Performance Evaluation Program for Mycobacterium tuberculosis Drug Susceptibility Testing is used to monitor and evaluate performance and practices among national laboratories performing M. tuberculosis susceptibility testing. Participation in this program is one way laboratories can ensure high-quality laboratory testing, resulting in accurate and reliable testing results.

Revision of this information collection provides CDC with an evaluation program to assess the ability of the laboratories to test for drug resistant M. tuberculosis strains, laboratories also have a self-assessment tool to aid in optimizing their skills in susceptibility testing. The information obtained from the laboratories on susceptibility practices and procedures is used to establish variables related to good performance,

assessing training needs, and aid with the development of practice standards.

Participants in this program include domestic clinical and public health laboratories. Data collection from laboratory participants occurs twice per year. The data collected in this program will include the susceptibility test results of primary and secondary drugs, drug concentrations, and test methods performed by laboratories on a set of performance evaluation (PE) samples. The PE samples are sent to participants twice a year. Participants also report demographic data such as laboratory type and the number of tests performed annually. There is no cost to respondents to participate other than their time. Total burden hours is 129.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Domestic Laboratories	Participant Biosafety Compliance Letter of Agreement	80	1	5/60
	MPEP Mycobacterium tuberculosis Results Worksheet	80	2	30/60
	Online Survey	80	2	15/60

	Instrument			
	Minimum Inhibitory Concentration (MIC) Results Form	4	2	15/60

Jeffrey M. Zirger,
Acting Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2018-27853 Filed: 12/21/2018 8:45 am; Publication Date: 12/26/2018]